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(54) **SAMPLING DEVICE AND SYSTEM FOR COLLECTING A SAMPLE OF A BODY FLUID**

(57) The application concerns a sampling device (12) and a system (10) for collecting body fluid, comprising a metal lancing unit (14) having a distal tip (40) suitable for piercing skin and a capillary channel (42) extending between the tip (40) and a proximal section of the lancing unit (14) for collecting body fluid; and further comprising

a plastic holding unit (16) affixed to the lancing unit (14) for manipulating the lancing unit (14) in order to form an incision in the skin, wherein the holding unit (16) contains a sorbent (38) adapted for sorption of moisture and/or volatile substances to protect the sampling device (12) from degradation prior to use.

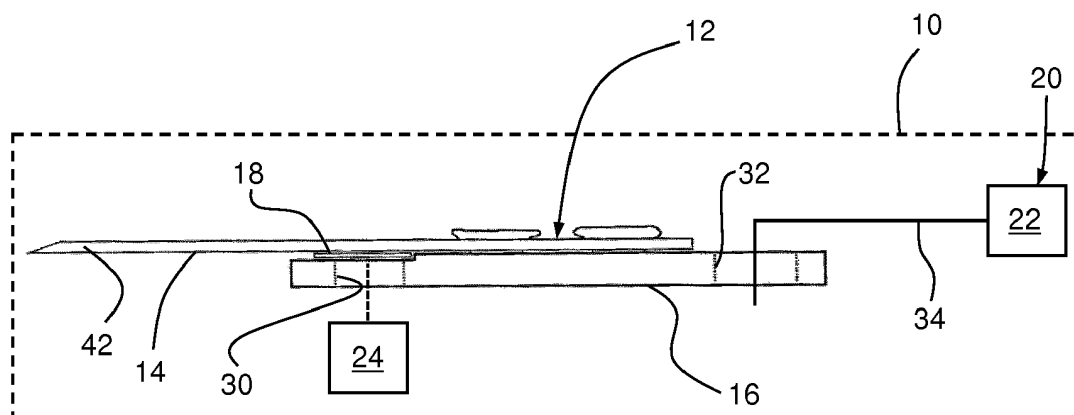


Fig. 1

Description

[0001] The invention concerns a sampling device for collecting a sample of a body fluid comprising a metal lancing unit having a distal tip suitable for piercing skin and a capillary channel extending between the tip and a proximal section of the lancing unit for collecting body fluid; and a plastic holding unit affixed to the lancing unit for enabling movement of the lancing unit in order to form an incision in the skin. The invention further concerns a sampling system including such a disposable sampling device.

[0002] In contrast to simple test strips for self-determination of blood glucose by patients, so-called integrated sampling devices and systems pursue a highly sophisticated concept of sample collection and analyte detection in one step in order to achieve an outstanding use convenience. Hitherto, integrated samplers have not reached the market, not only due to economic reasons. Due to the contamination with sample and the irreversible detection chemistry, the samplers have to be construed as low-cost disposables only for single use. Specific problems are caused by ambient influences which may lead to degradation during storage, in particular due to substances permeating or emanating from containers and interfering capillary action or detection means. Other problems are due to engagement of metallic structures during motion sequences which over the time may lead to abrasion and obstruction of driving elements.

[0003] On this basis the object of the invention is to further improve the known devices and systems and to define a design which provides for improved functional stability and safety while avoiding malfunction of actuated parts.

[0004] The combination of features stated in the independent claims is proposed to achieve these objects. Advantageous embodiments and further developments of the invention are derived from the dependent claims.

[0005] The invention is based on the idea of providing a sampling device with an improved multifunctional component. Thus, it is proposed according to the invention that the holding unit contains a sorbent material adapted for sorption of moisture and/or volatile substances to protect the device from degradation prior to use. The plastic holding unit allows for easy integration of the sorbent to protect the individual sampling device. In particular, the sorbent may help to maintain the hydrophilicity of the capillary channel and to avoid moisture-induced degradation of a test chemistry that may be arranged on the device. Furthermore, the holding unit being made of a plastic material does not only allow for cost-effective production of a handling means, but also reduces abrasion of metal parts of an engaging actuation mechanism.

[0006] The term "volatile substances" as used within the present application comprises substances which have a vapor pressure of ≥ 0.1 kPa at a temperature of 20°C. Typical examples of volatile substances in the sense of the present application are hydrophobic, organic

chemical substances having a molecular weight between 100 and 1000 Daltons.

[0007] Advantageously, the sorbent is selected from the group consisting of carbon black, activated carbon, graphite, desiccant polymers, silica gel, zeolites, ion exchange resins, molecular sieve materials. This allows to adsorb or absorb a variety of interfering substances, in particular moisture from the ambient air and monomers released from containers and the like.

[0008] For further improvement it is advantageous when the sorbent is dispersed in the material of the holding unit or disposed therein or coated thereon.

[0009] Another manufacturing improvement is achieved when the holding unit is formed as an injection molded component from a molding composition containing the sorbent.

[0010] According to a preferred implementation, the holding unit comprises a plastic structure adapted for releasable engagement of an actuation mechanism. Thus, while avoiding scratches or abrasion on metallic structures, the function of a metal actuator can be retained over time.

[0011] Another improvement provides that the plastic structure is formed as a hole or a recess in the holding unit.

[0012] Preferably, the lancing unit is formed from an elongate piece of a flat material, in particular from a sheet of stainless steel.

[0013] For further improvement of liquid sample-up-take, it is also preferred that the capillary channel is provided as a groove or slit which is laterally open to the outside on one side or on two opposite sides.

[0014] A particular embodiment further comprises a test element adapted for detecting at least one analyte in the body fluid and arranged to receive body fluid via the capillary channel. Thereby, the sample can be analyzed "on-board" without significant delay.

[0015] According to another preferred implementation, the test element is supported between the holding unit and the lancing unit in fluidic connection to the capillary channel. In this configuration, the test element is maintained in direct vicinity of the sorbent, and the test chemistry thereon may even support the suction of sample by capillary action.

[0016] For further design improvement it is advantageous when the test element is retained on a surface area of the holding unit and the surface area confines a measuring window for an optical detection of the analyte.

[0017] For providing a functional final product, it is advantageous when the holding unit is fixedly connected to a proximal part of the lancing unit by means of form-locked connecting elements, in particular by riveted pins.

[0018] Another aspect of the invention concerns a sampling system for collecting a sample of a body fluid comprising at least one sampling device according to the invention and further comprising an actuation mechanism which is operable to drive a lancing movement of the lancing unit, wherein the actuation mechanism com-

prises a metallic driving member adapted to engage a plastic structure of the holding unit. In this way, the advantages elucidated above are achieved in analogous way within an instrument adapted for use of disposable devices preferably provided in a magazine.

[0019] Preferably, the metallic driving member is formed by a gripper or hook, such that gripping and movement of individual sampling devices is simplified.

[0020] In this connection it is also advantageous when the plastic structure is provided as a hole or a recess in the holding unit.

[0021] In the following, the invention is further elucidated on the basis of an embodiment example shown schematically in the drawings, where

Fig. 1 is a schematic view of a sampling system comprising an integrated microsampler for collecting and measuring body fluid;

Fig. 2 is a sectional view of a plastic holding unit of the microsampler;

Fig. 3 is a top view of the holding unit of Fig. 2;

Fig. 4 is a bottom view of a metal lancing unit of the microsampler including a capillary channel;

Fig. 5 is a side view of the holding and lancing unit in a pre-assembled state.

[0022] Fig. 1 shows a sampling system 10 provided for collection of a sample of a body fluid (e.g. blood) and detection of at least one analyte (e.g. glucose) in the body fluid. The system 10 comprises at least one disposable sampling device (integrated microsampler 12) consisting of a metal lancing unit 14, a plastic holding unit 16 and a test element 18. The system 10 further comprises a preferably portable meter 20 including an actuation mechanism 22 for a reciprocating lancing movement of the microsampler 12 in and out the skin of a user and a measuring unit 24 for a reflectometric optical measurement on the test element 18.

[0023] As shown in more detail in Fig. 2 and 3, the holding unit 16 comprises a flat base part 26 having a rectangular outline. On a central section, two upright pins 28 are molded thereon at a distance from each other. In the distal section, a through-hole is provided as a measuring window 30. The proximal section comprises an oblong hole 32 which allows engagement of a metallic hook 34 of the actuation mechanism 22.

[0024] The holding unit 16 is formed as an injection molded component from a molding composition which contains a thermoplastic base material 36 and a sorbent material 38 for sorption of moisture and/or volatile substances to protect the microsampler 12 from degradation prior to use. For example, carbon black may be dispersed in the molding composition.

[0025] Fig. 4 shows the lancing unit 14 as a separate

part prior to assembly with the holding unit 16. The lancing unit 14 is formed from a sheet of stainless steel by chemical milling or edging. Further details of such a manufacturing process may be found in EP-A 1671585, which is incorporated by reference herewith.

[0026] As further apparent from Fig. 4, the lancing unit 14 is provided with a sharp tip 40 at its distal end, i.e. the end pointing to the skin in use. In this way, an incision can be formed in the skin in order to collect the body fluid. A capillary channel 42 in the lancing unit 14 allows to transport a small amount of body fluid from the tip to a proximal sampling section 44. For this purpose, the capillary channel 42 extends in the longitudinal direction of the elongate lancing unit 14 and is formed as a groove which is laterally open on the bottom side of the lancing unit 14. It is conceivable that the capillary channel is widened in the sampling section 44. The depth of the groove may be in the range of 50 to 80 μm .

[0027] In order to support the liquid uptake and transport, the capillary channel 42 may be coated with a hydrophilic agent or with a suspension containing nanoparticles.

[0028] Such nanoparticles may comprise particles having a silicon dioxide structure as described in the claims of WO 2012/126945.

[0029] Examples of hydrophilic agents are

- non-ionic tensides, such as polysorbate,
- hydrophilic metal oxides, e.g. AlOOH , TiO_x , SiO_2 ,
- organic polymeric compounds, such as PVP-PEG,
- water-soluble organic polyacids or salts thereof, such as polyacrylic acid or heparin salts, dextran sulfate, chondroitin sulfate.

[0030] For a defined form-locking connection to the pins 28 of the holding unit 16, two separate holes 46 are provided on the lancing unit 14 at a distance in the longitudinal direction thereof.

[0031] Further depicted in Fig. 4 is the test element 18 which is arranged in fluid connection with the sampling section 44 of the capillary channel 42. The test element 44 consists of a pad 48 coated with a dry test chemistry which is responsive to the analyte by an irreversible color change.

[0032] Fig. 5 shows the microsampler 12 in a pre-assembled state where the pins 28 reach through the holes 46 and the bottom side of the lancing unit 14 rests flat on the top side of the holding unit 16. Then, in order to provide for a firm connection, the heads of the pins 28 are pressed flat to provide a riveted joint, as shown in Fig. 1.

[0033] As further illustrated in Fig. 5, the test element 18 is arranged on a surface area 50 of the holding unit 16 which confines the measuring window. Thus, the body fluid is supplied from the capillary channel 42 to the top side of the test pad 48, whereas the optical measurement can be performed through the window 30 on the rear side of the test pad 48.

[0034] In this configuration, the sorbent material 38 of

the holding unit 16 adsorbs interfering substances during storage of the microsampler 12. Such substances may include moisture which would disturb the dry setting of the reactive chemistry on the test pad 48. Furthermore, the sorbent material 38 may be furnished to adhere monomers emitted by a container of the microsampler which could lead to a degradation of the hydrophilic properties of the capillary channel 42.

[0035] In use, the microsampler 12 is ejected in distal direction out of a guiding chamber of the meter 20 against the skin of the user. After collection of the sample, the microsampler 12 is retracted to perform the measurement. Such lancing movement is driven by means of the metallic hook 34 which is guided by the plastic material of the holding unit 16 surrounding the oblong hole 32, thereby preventing wear by avoiding a metal-to-metal contact.

Claims

1. Sampling device for collecting a sample of a body fluid comprising

- a metal lancing unit (14) having a distal tip (40) suitable for piercing skin and a capillary channel (42) extending between the tip (40) and a proximal section of the lancing unit (14) for collecting body fluid;
- a plastic holding unit (16) affixed to the lancing unit (14) for manipulating the lancing unit (14) in order to form an incision in the skin;

characterized in that

- the holding unit (16) contains a sorbent (38) adapted for sorption of moisture and/or volatile substances to protect the sampling device (12) from degradation prior to use.
2. The sampling device of claim 1, wherein the sorbent (38) is selected from the group consisting of carbon black, activated carbon, graphite, desiccant polymers, silica gel, zeolites, ion exchange resins, molecular sieve materials.
 3. The sampling device of claim 1 or 2, wherein the sorbent (38) is dispersed in the plastic material (36) of the holding unit (16) or disposed therein or coated thereon.
 4. The sampling device according to any of claims 1 to 3, wherein the holding unit (16) is formed as an injection molded component from a molding composition containing the sorbent (38).
 5. The sampling device according to any of claims 1 to 4, wherein the holding unit (16) comprises a plastic

structure (32) adapted for releasable engagement of an actuation mechanism.

6. The sampling device of claim 5, wherein the plastic structure (32) is provided as a hole or a recess in the holding unit (16).
7. The sampling device according to any of claims 1 to 6, wherein the lancing unit (14) is formed from an elongate piece of a flat material, in particular from a sheet of stainless steel.
8. The sampling device according to any of claims 1 to 7, wherein the capillary channel (42) is provided as a groove or slit which is laterally open to the outside on one side or on two opposite sides.
9. The sampling device according to any of claims 1 to 8, further comprising a test element (18) adapted for detecting at least one analyte in the body fluid and arranged to receive body fluid via the capillary channel (42).
10. The sampling device of claim 9, wherein the test element (18) is supported between the holding unit (16) and the lancing unit (14) in fluidic connection to the capillary channel (42).
11. The sampling device of claim 9 or 10, wherein the test element (18) is retained on a surface area (50) of the holding unit (16) and the surface area (50) confines a measuring window (30) for an optical detection of the analyte.
12. The sampling device according to any of claims 1 to 11, wherein the holding unit (16) is fixedly connected to a proximal part of the lancing unit (14) by means of form-locked connecting elements (28), in particular by riveted pins.
13. A sampling system for collecting a sample of a body fluid comprising at least one sampling device (12) according to any of the previous claims and further comprising an actuation mechanism (22) which is operable to drive a lancing movement of the lancing unit (14), wherein the actuation mechanism (22) comprises a metallic driving member (34) adapted to engage a plastic structure (32) of the holding unit (16).
14. The sampling device of claim 13, wherein the metallic driving member (34) is formed by a gripper or hook.
15. The sampling device of claim 13 or 14, wherein the plastic structure (32) is provided as a hole or a recess in the holding unit (16).

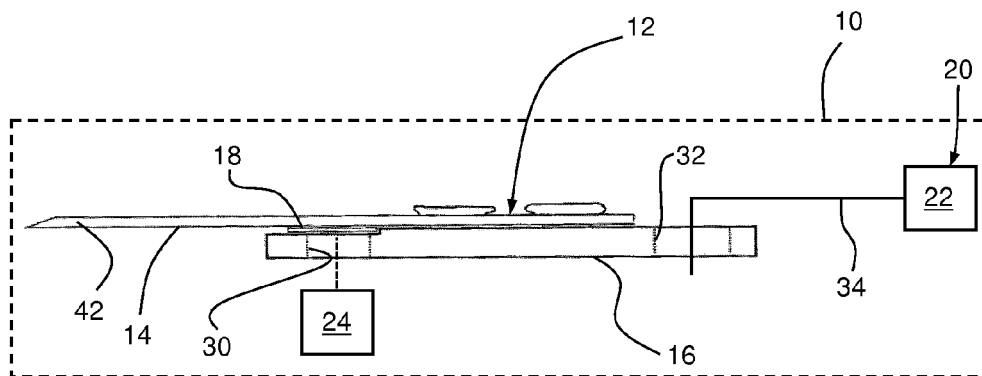


Fig. 1

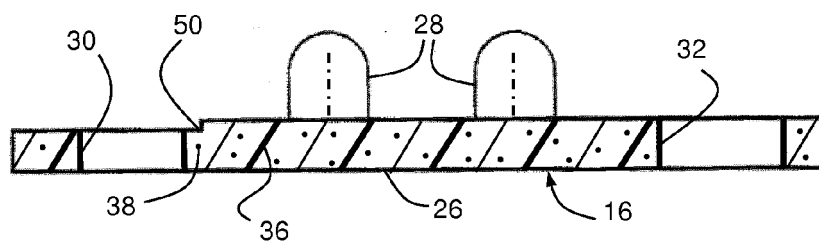


Fig. 2

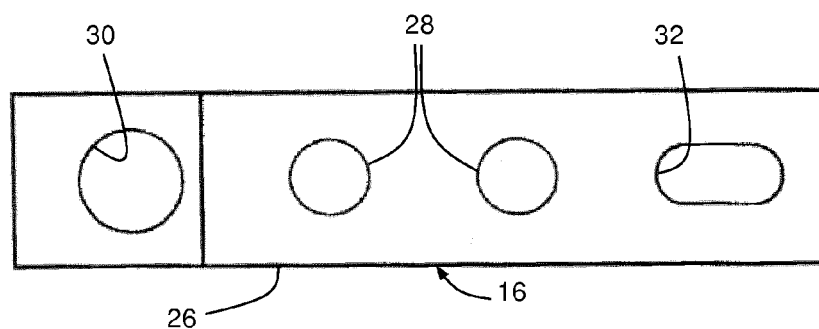


Fig. 3

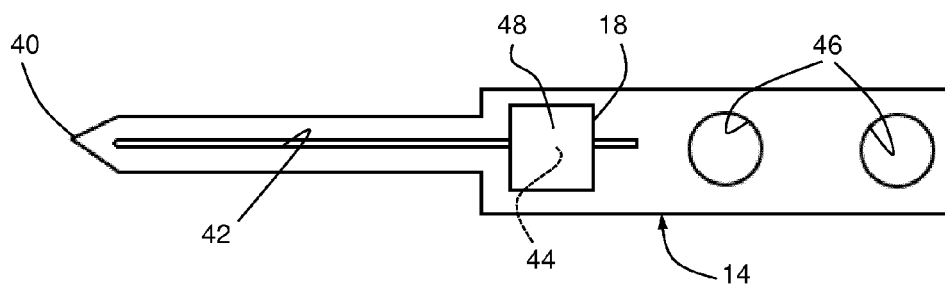


Fig. 4

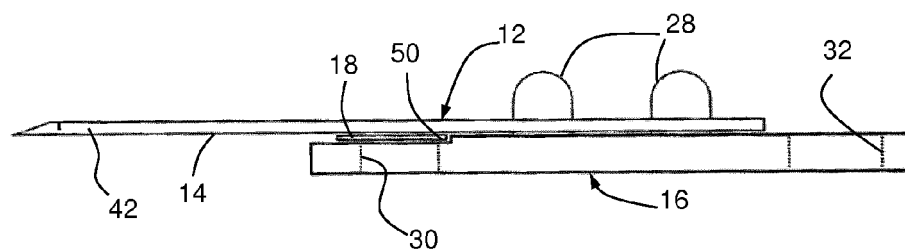


Fig. 5



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